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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,660	09/01/2005	Per Hofvander	12810-00125-US	1628

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EXAMINER

PAGE, BRENT T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/547,660

Applicant(s)

HOFVANDER ET AL.

Examiner

Brent Page

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 8, 12, 14 and 15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-11, 16-19 and 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/01/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group II and SEQ ID NO:3 and SEQ ID NO:4 in the reply filed on 10/06/2006 is acknowledged. The traversal is on the ground(s) that the technical feature linking the inventions make a contribution over the prior art. This is not found persuasive because by Applicants own admission in Applicants arguments the biosynthetic genes are merely "preferably" from *Solanum tuberosum* and the genes may be the claimed SEQ ID NOs or "homologs or orthologs thereof", which broaden the scope of the invention to starch biosynthetic genes. Additionally Applicants agree in the arguments that the concept of starch biosynthesis enhancing genes is the technical feature linking the inventions and argue that the cited reference of Tanaka et al does not teach this feature. The Examiner respectfully disagrees and maintains that a starch synthase from rice is a starch biosynthesis enhancing protein.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 5-7, 9 and 16-27 are objected to because of the following informalities: The claims are drawn to non-elected subject matter. The claims still recite non-elected sequences, or depend from claims that recite non-elected sequences. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1638

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-11, 16-19, and 22-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:3 and corresponding SEQ ID NO:4, does not reasonably provide enablement for any starch biosynthesis enhancing protein, less than 100% sequence identity proteins, fragments, variants, and naturally occurring variants as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of increasing the production of starch in plants comprising culturing a plant with enhanced expression or activity of any starch biosynthesis enhancing protein wherein the amylose production is increased and the starch has a higher amylose content and the method comprises over-expression of said starch biosynthesis enhancing protein, wherein the plant is potato. The claims are also drawn to a transgenic expression cassette comprising a nucleic acid sequence comprising a fragment of at least 30 nucleotides of a nucleic acid sequence comprising SEQ ID NO:3, or a nucleic acid that encodes a polypeptide comprising an amino acid sequence at least about 50% identical to the amino acid sequence of SEQ ID NO:4, or a nucleic acid sequence that encodes a fragment of a polypeptide comprising SEQ ID NO:4 wherein the fragment comprises at least 10 contiguous amino acid residues of the SEQ ID NO:4 or a nucleic acid sequence encoding a naturally occurring variant of a polypeptide comprising SEQ ID NO:4. With regard to claims reciting less than 100% sequence identity, the breadth of the claims encompasses unspecified base/amino acid

additions, deletions, substitutions and combinations thereof while retaining starch biosynthesis enhancing activity. These fragments and variants would also necessarily encompass antisense molecules.

In contrast, the specification only provides guidance for the over expression of the full-length nucleic acid sequences of SEQ ID NO:1 and SEQ ID NO:3 that leads to the increase in amylose content of potatoes. The specification does not provide guidance for any variants, fragments, antisense molecules, or homologs of the nucleic acids of SEQ ID NO:1 and SEQ ID NO:3. The specification also does not provide any guidance or working examples of sequences having less than 100% sequence identity to SEQ ID NO:3 or the corresponding amino acid sequence of SEQ ID NO:4. Applicant also provided no guidance as to which region or regions of SEQ ID NO:4 should be retained for function.

The effect of starch biosynthesis genes on amylose content and structure is unpredictable. Recent studies have shown that GBSSI genes in many plant species have more than one isoform, and further that different isoforms are present in different plant tissues and therefore have different effects on the starch content of the endosperm. Patron et al (Plant Physiology 2002, 130: 190-198) disclose a study detailing the altered pattern of amylose accumulation in low-amylose barley cultivars with mutant alleles of the different isoforms of barley GBSSI (see page 190 1st full paragraph, page 191, last full paragraph, page 192, last full paragraph). Edwards et al (The Plant Cell 2002, 14: 1767-1785) disclose the characterization of the discrete forms of amylose produced by different isoforms of GBSSI in pea (see page 1767, last full

Art Unit: 1638

paragraph, page 1768 1st and second full paragraphs, page 1771 3rd full paragraph, and page 1775 in its entirety). Given the unpredictability for different isoforms of a protein in transgenic plants, it would likewise be unpredictable to determine the effect unspecified length and sized fragments would have on the starch biosynthesis pathway as broadly claimed. Additionally, claimed variants including sequences with less than 100% sequence identity to SEQ ID NO:3 would not be enabled for the same unpredictable nature as discussed above when taken together with the lack of guidance discussed above.

The effect of the expression of antisense molecules on the expression of a corresponding gene and its function is unpredictable. Heuer et al (Plant Physiology 2001 127:33-45) disclose the transformation of maize plants with a *ZmMADS3* antisense construct that encompassed the 3' untranslated portion of the *ZmMADS3* gene, known for its importance in organ development. Heuer et al learned that no phenotypic change was observed in plants carrying and expressing the antisense DNA (see page 37, last paragraph).

Given the state of the art, the disclosures by Patron et al, Edwards et al, and Heuer et al, and the unpredictability as discussed above, it would have been undue experimentation for one of skill in the art to evaluate all the claimed gene fragments and variants for their effect on amylose content.

Claims 1-6, 9-11, 16-19, and 22-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to

Art Unit: 1638

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of increasing the production of starch in plants comprising culturing a plant with enhanced expression or activity of any starch biosynthesis enhancing protein wherein the amylose production is increased and the starch has a higher amylose content and the method comprises over-expression of said starch biosynthesis enhancing protein, wherein the plant is potato. The claims are also drawn to a transgenic expression cassette comprising a nucleic acid sequence comprising a fragment of at least 30 nucleotides of a nucleic acid sequence comprising SEQ ID NO:3, or a nucleic acid that encodes a polypeptide comprising an amino acid sequence at least about 60% identical to the amino acid sequence of SEQ ID NO:4, or a nucleic acid sequence that encodes a fragment of a polypeptide comprising SEQ ID NO:4 wherein the fragment comprises at least 10 contiguous amino acid residues of the SEQ ID NO:4 or a nucleic acid sequence encoding a naturally occurring variant of a polypeptide comprising SEQ ID NO:4.

In contrast, the specification only provides guidance for the over expression of the full-length nucleic acid sequences of SEQ ID NO:1 and SEQ ID NO:3 that leads to the increase in amylose content of potatoes. The specification does not provide guidance for any variants, fragments, or homologs of the nucleic acids of SEQ ID NO:1 and SEQ ID NO:3.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a

Art Unit: 1638

precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not

reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 9-11, 16-19 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al (US Patent 5750876).

The claims are broadly drawn to a method of increasing the production of starch in plants comprising culturing a plant with enhanced expression or activity of any starch biosynthesis enhancing protein wherein the amylose production is increased and the

Art Unit: 1638

starch has a higher amylose content and the method comprises over-expression of said starch biosynthesis enhancing protein, wherein the plant is potato and the transgenic expression cassette used therein, wherein the promoter is heterologous and tuber specific. For the purposes of examination claim 6 and 16 both recite the limitation of a nucleic acid sequence comprising a fragment of at least 30 nucleotides of a nucleic acid sequence comprising the nucleotide sequence of SEQ ID NO:3 and are interpreted to read on any sequence comprising at least 30 nucleotides in any order that are in common with any sequence that may comprise SEQ ID NO:3, which reads on any sequence that has a length of more than 30 nucleotides.

Barry et al teach a method for the production of isoamylase, a DNA construct, a transformed potato plant with said construct, wherein the promoter is the tuber-specific promoter of the patatin gene, and the gene is the starch biosynthesis enhancing ADPglucose pyrophosphorylase gene, wherein the amylose content of the starch is increased which would inherently increase the production of starch in plants (see claims 5-6, 10, 15-17, the abstract, Column 3 lines 48-51, and Column 12, lines 11-14, for example). The ADPglucose pyrophosphorylase gene would also inherently comprise a fragment of at least 30 nucleotides of a nucleic acid sequence comprising SEQ ID NO:3 since the 30 nucleotides are not specified as being *contiguous*.

Conclusion

Claim 13 is allowed.


Art Unit: 1638

Claims 7, 13, and 20-22 are free of the prior art given the failure of the prior art to teach or fairly suggest SEQ ID NO:3, SEQ ID NO:4, a transgenic expression cassette comprising SEQ ID NO:3, or a nucleic acid encoding SEQ ID NO:4 or a natural variant thereof or a method of increasing the production of starch comprising culturing a plant with SEQ ID NO:3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


PHUONG T. BUI
PRIMARY EXAMINER